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Changing Malaria Treatment Policy to Artemisinin-Based Combinations: An Implementation Guide

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Rational Pharmaceutical Management Plus
Center for Pharmaceutical Management
Management Sciences for Health
4301 N. Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Phone: 703-524-6575
Fax: 703-524-7898
E-mail: rpmplus@msh.org
www.msh.org/rpmplus

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Guide Contributors

Grace Adeya, RPM Plus, Management Sciences for Health (MSH)
Maryse Dugue, RBM Department, World Health Organization
Michael Gabra, RPM Plus, MSH
Paul Lalvani, Global Fund to Fight AIDS, Tuberculosis and Malaria
David Lee, Center for Pharmaceutical Management, MSH
Evan Lee, MSH Europe
Maria Miralles, RPM Plus, MSH
Rima Shretta, RPM Plus, MSH

About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning, as well as in promoting the appropriate use of health commodities in the public and private sectors.

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Rational Pharmaceutical Management Plus Program
Center for Pharmaceutical Management
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Phone: 703-524-6575
Fax: 703-524-7898
E-mail: rpmplus@msh.org
Web site: www.msh.org/rpmplus

CONTENTS

ACRONYMS

ACT	artemisinin-based combination treatment
BCC	behavior change communication
DHS	Demographic and Health Surveys
EML	Essential Medicines List
GF, GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
HMIS	health management information system
IEC	information, education, and communication
IMCI	Integrated Management of Childhood Illnesses
ITN	insecticide-treated nets
LLITN	long-lasting insecticide-treated net
M&E	monitoring and evaluation
MMSS	Malaria Medicines Supply Service
MOH	Ministry of Health
MSH	Management Sciences for Health
NGO	nongovernmental organization
RBM	Roll Back Malaria [Partnership]
RDT	rapid diagnostic tests
RPM Plus	Rational Pharmaceutical Management Plus Program
STGs	standard treatment guidelines
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
WHO	World Health Organization

BACKGROUND

The decision to change the antimalarial treatment policy and the subsequent implementation of the policy brings with it challenges and complexities at every level, involving a variety of stakeholders, ranging from departments within the Ministry of Health (MOH) to manufacturers and private providers.

The World Health Organization (WHO; 2004) recommends that all countries, in revising malarial treatment policies, opt for a combination treatment, preferably an artemisinin-based combination therapy (ACT). In accordance with this recommendation, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) has given countries that have in place signed grants covering proposals for malaria treatment during rounds 1, 2, and 3 the option to consider reprogramming their requests for funds for treatment to be directed for ACTs. For this purpose, the GFATM has made additional funds available for the procurement of ACTs.[1] Countries submitting proposals for reprogramming of existing grants or for new grants must ensure that the procurement and programmatic costs of implementing the change are considered. For countries that have unacceptable levels of resistance to their current antimalarial therapies, covering such costs is critical, and the development of a sound plan for reprogramming that takes into account procedural, regulatory, procurement, and other drug management elements will be essential.

Although there are some guidelines and documents on the elements that need to be considered when changing first-line treatment (including the levels of drug resistance considered acceptable before countries should begin the process of review) (WHO/AFRO 2003), little guidance exists on the steps required when rolling out a new treatment policy for national-level implementation. While each step for formulation and rolling out a new treatment policy is described here in some detail, further details on implementing a change are available from other sources (MSH and WHO 1997); technical assistance from Roll Back Malaria (RBM) partners is also available.

Objective

The purpose of this document is to provide guidance to countries on the actions that need to be taken when considering changing its national policy for the first-line treatment for malaria to an ACT consistent with WHO recommendations as well as implementing the change. It addresses operational and technical considerations for both the public and private sectors, and it may be used as a planning tool to identify technical assistance and resource needs.

This document focuses on the implementation process after a decision is made to change the treatment policies. Some documents providing guidance on achieving the policy change are listed in Annex 4.

[1] The criteria for eligibility for reprogramming will be provided elsewhere.

INTRODUCTION

The change in treatment policy may be said to occur in four phases—

- The policy review and change process: the processes and procedures leading up to the selection of the new treatment policy, including discussions on financing
- The transition phase: the period when the decision on the new treatment policy has been made but the implementation of the policy has not yet occurred
- The full implementation of the new policy: national rollout of the new policy[2]

This document focuses on the transition phase, and in developing this document, the following assumptions have been made concerning the policy change process—

1. The selection of an effective first-line treatment for malaria consistent with the WHO recommendations has been made and this selection occurred in consultation with all the RBM partners in the country, MOH departments (including Integrated Management for Childhood Illness [IMCI], reproductive health, and regulatory authorities), as well as other stakeholders that would be involved in the implementation of the new policy.

2. The decision on the diagnostic criteria for malaria—that is, whether to use clinical diagnosis or biological diagnosis (microscopy, rapid diagnostic tests [RDTs])—has been made as part of the policy change process. This decision is important in determining what drugs and other commodities to purchase, and their quantities.

3. The decision on what dosage forms to use—that is, whether to use a coformulated, prepackaged, or loose combination of drugs that are coadministered—has been made as part of the new treatment policy.

4. An existing mechanism or structure incorporates all the stakeholders involved in the implementation of the new policy. This mechanism or structure will be responsible for planning and coordinating the implementation process. The formation of a transition committee responsible for piloting the process can be useful. Although the "ownership" of policy change and implementation lies with the MOH, other stakeholders are involved in this process. An illustrative list of stakeholders is shown in Box 1.

[2] The implementation of the new policy can be done either through a phased implementation or through an immediate nationwide rollout.

Box 1: Illustrative List of Stakeholders

This list should be tailored to the specific context in each country.

Ministry of Health
- National Malaria Control Program
- Pharmacy and Essential Drugs Department
- Health Education Department
- Provincial and District Health Officers
- Director of Reproductive Health
- Director of the IMCI Program

Ministry of Finance
- Director of Health Budgets

Private Sector
- Manufacturers of antimalarials and diagnostic products
- Importers and wholesalers
- Private hospitals and pharmacies
- Drug shops
- Traditional healers

Research Departments and Institutions
- Department of Epidemiology
- Pharmacy Department

Professional Organizations

Nongovernmental Organizations (including mission hospitals

Before beginning the process of policy implementation, it is critical to ensure that the financing issues have been addressed.

Financing

Effective transition and implementation of the new policy is likely to require a time-limited investment of additional resources—including resources for the development and printing of clinical guidelines and behavior change communication (BCC) materials, plus costs for training and for the other activities described below—in addition to the recurrent incremental cost for the procurement of the new antimalarial treatment. These costs should be budgeted at the planning stage. Commitments from departments within the country and from donors need to be sought before beginning the implementation process. Although the incremental cost for the purchase of the antimalarials is simple to define, the costs for the transition process will vary significantly with country context. Goodman and colleagues (2001) calculated the transition process in Tanzania to cost U.S. dollars (USD) 450,000.

Box 2: Key Questions about Financing Strategies

- What are the financial requirements for transitioning to the new policy, and what is available?
- Has a financing strategy been developed?
- Do the financing strategies protect the most vulnerable?
- Are financial accountability mechanisms in place, and how well do they work?

Financial resources that may be used for national-level procurements include funds from national government budgets (including district grant funds); from multilateral and bilateral institutions such as the World Bank and GFATM, from nongovernmental organizations (NGOs); and from other foundations. These funds should be coordinated to cover the comprehensive plan and should be used not only for the direct purchase of antimalarials, but also to improve the diagnosis of malaria and to strengthen health systems to deliver the treatment effectively and efficiently. This implementation guide will help identify some of the technical assistance and resource needs required for the implementation.

In countries where cost-recovery systems already exist, these systems are based on a cost structure that depends on the cheaper antimalarials currently in use. The introduction of the more expensive ACTs means that these cost structures may need to be reviewed in light of the anticipated increase in costs; in addition, countries may need to explore alternatives for reducing the increased cost burden on the most vulnerable populations to ensure that ACTs are available and affordable for even the poorest population groups.

In addition, mechanisms used to ensure financial accountability must be put into place through the development of an appropriate financial management system.

FRAMEWORK FOR IMPLEMENTATION OF ACT POLICY

This framework focuses on the key components needed during the transition phase of the new policy, as illustrated in Box 3. The framework addresses these components as they might affect the implementation of the policy in the public sector as well as the private sector. The private sector includes the not-for-profit institutions (i.e., faith-based and secular NGOs) as well as commercial or for-profit shops and organizations.

The key components in the implementation of the new policy can be divided into the technical components and the operational components. The technical components incorporate the activities related to the selection of the drugs and the regulatory changes that must occur as a result, and appropriate use of the new drugs. As discussed earlier, this guidance document assumes that decisions related to the selection of the drug have been discussed during the policy change process. This guidance document therefore focuses on ensuring the appropriate use of the new treatment through the development and dissemination of new guidelines consistent with the new policy, as well as the development and use of appropriate training and BCC strategies. The operational components incorporate the activities related to procurement and supply chain management, which ensure that the new drugs are available at the points of service delivery.

Box 3. Key Components in Framework for Implementation of the ACT Policy

1. **Technical considerations**
   - Revision of Drug Regulation
   - Development/Review of the Essential Medicines List (EML), the Standard Treatment Guidelines (STGs) and/or other relevant guideline document and BCC materials for malaria
     - Dissemination of the revised STGs and/or other relevant guideline document and BCC materials
     - Training and supervision of health workers consistent with the new guidelines
     - Information, Education, and Communication (IEC) targeting the community
2. **Operational considerations**
   - Management of stock of antimalarials currently in use
     - Development of a phase-out plan
   - Management of ACT Supply
     - Forecasting of demand and quantification
     - Procurement
     - Distribution
     - Inventory Management
   - Review of Quality Assurance Mechanisms
     - Pharmacovigilance
     - Product Quality Surveillance
3. **Monitoring and evaluation**

The following sections of this document outline and briefly discuss the technical and operational issues.

Technical Considerations

Revision of Drug Regulation

Three key questions must be addressed during the policy change process for the subsequent implementation of the policy to be successful; these are outlined in Box 4.

Box 4. Key Drug Regulatory Questions

- Have issues regarding the registration of ACTs in the country been addressed?
- Are the regulations pertaining to the prescribing and dispensing of ACTs in the country consistent with the adopted policy?
- Are the regulations regarding the distribution and sale of ACTs consistent with the policy?

The new therapies selected must be authorized for sale on the market. In most countries, authorization involves a drug registration process that includes the submission of a dossier of information on efficacy, safety, and other properties. For combination therapies, information on the different registration requirements for fixed-dose combinations, copackaged combinations, and coadministered combinations must be obtained early enough to allow an adequate lead time in the transition process. For example, in Kenya, new fixed-dose combinations and new prepackaged products must be registered even if the individual components of the combination are already registered (Shretta 2002).

The registration process can take three months or more depending on how often the registration committee in the country meets. If the new therapy is not registered, most countries have mechanisms to waive and/or fast-track the registration process for public sector programs.

If donations of ACT in kind are accepted, they should comply with the country's drug donation guidelines. If these guidelines do not exist in the country, WHO Drug Donation guidelines should be followed. This is particularly important given the variation among different formulations of ACT and their short shelf life.

Regulatory changes, to be implemented by the competent authorities of the MOH, such as the Drug Transition Committee or other body, in conjunction with the National Formulary Committee and Drug Regulatory Authority, include changes in drug scheduling[3] to ensure the availability of the new first- and second-line drugs at public and private health facilities, such as pharmacies, clinics, and dispensaries (in the public sector) and over-the-counter shops, *dépôts*

[3] This is the legal status of a drug (e.g., prescription-only medicine, over-the-counter medicine).

pharmaceutiques, *duka la dawa*, or chemical sellers (in the private sector), where this will be consistent with the new policy.

There should also be a plan to phase out and remove the previous antimalarial drugs from the system. Legislation for the removal or "banning" of the previous antimalarial drug raises several complexities and it may be necessary to explore alternative strategies, such as rescheduling of the antimalarial to a prescription-only medicine, which may reduce the demand for the previous drug over time. Such legislative changes can take up to six months or more, depending on the country context and the process required for instituting such a change.

Revision of the STGs and EML

Revision of the STGs and EML must be coordinated with the development of the BCC to ensure that the same messages are communicated to health care workers and members of the public. The key questions to ask when developing the communication components of the implementation plan are listed in Box 5.

Box 5. Key Questions on the Communication Components in Implementing the New Policy

- Are there existing STGs and EMLs that need to be updated? Who will be responsible for updating the STGs and EMLs or developing new ones?
- How will the revised STGs and EMLs be disseminated within the public sector and the private sector?
- What training will be provided to health workers to familiarize them with the new policy? Who will develop the training materials and carry out the training for both the public and private sectors?
- Who is responsible for development of the BCC strategies, and how will this be coordinated with the development, dissemination, and training of the revised STGs?
- Who is responsible for development of the IEC materials and strategies, and how will this be coordinated with the BCC strategies?

The malaria sections of the STGs and EML, Integrated Technical Guidelines such as IMCI modules, any guides for health workers, curricula or handbooks, and any other guidelines or documents recommending treatments for malaria will need to be revised.[4] For all these materials, it may not be possible to publish new documents as soon as guidelines are revised. In this case, countries may choose to publish an addendum to replace the relevant section in the original guidelines. In all the above documents, the time needed for the processes to complete the documents as well as printing and publishing must be planned for. This process can take between three and six months. The time needed should be determined before development of an action plan.

[4] Guidelines for antenatal care for the treatment of malaria during pregnancy also need to be revised to include intermittent preventive therapy for malaria prevention if this policy is adopted.

Dissemination of STGs and Training of Health Workers

A plan must be developed for the dissemination of the revised STGs and must include the dissemination of the guidelines to both the public and private sectors as well as the sensitization, training, or both of the health workers on these new guidelines. Work will need to be done with *pre-service* training institutions, to incorporate revisions to antimalarial treatment in their curricula. Similar changes need to be made to IMCI and other *in-service* training curricula used in the country. Training/sensitization activities of health workers must be done shortly before the new first-line antimalarial is available at the health facility level. Carrying out the training too early has negative effects; providers may begin recommending the new treatment before it is available and/or they may forget the key messages emphasized during the training when the drugs finally are available. Carrying out the training too late, after the antimalarials are available at the health facilities, may lead to inappropriate or irrational use of the ACTs.

BCC/IEC Strategies

Implementation of a drug change, particularly to therapies with which providers and patients have little experience, requires considerable planning for behavior change strategies and capacity building at all levels. Activities must be undertaken to raise *public awareness* about the change in the first-line antimalarial treatment using multiple approaches, including print, mass media, and drama. These activities can also be used to convey other key malaria messages. It is crucial to ensure that these BCC/IEC campaigns are coordinated with the sensitization/training of health workers on the new policy to ensure that the same messages are being communicated to all.

Operational Considerations

Management of Stocks of Antimalarials Currently in Use: Developing a Phase-Out Plan

This area is critical, because countries are often reluctant to change treatments when they have large pipelines of "old" drugs in the system. For this reason, provisions for phasing out of the previous drug must be made during the transition phase to avoid wastage when the new policy is implemented. Some key questions that must be asked in developing a plan for phasing out the current antimalarial from the system are listed in Box 6.

Box 6. Key Questions in Developing a Phase-Out Plan for Removing the Current Antimalarial Drug from the Health System

- What system will be established to remove the current antimalarial supplies from the public sector facilities once the new ACT products are available?
- What, if anything, will be done about the existing pipelines of the current antimalarial in the private sector?

As part of the phase-out plan, accurate estimates of the current first-line treatments in stock and in the pipeline must be compiled, and future procurements should be adjusted to ensure that when the switch to the new drug is made, there is not a large stock of the previous drug in the system. Data on pipelines can be obtained from the central medical stores, district stores, and health facilities though a request by letter from a recognized authority. The procurement agency will often be aware of any drugs in the pipeline that have not arrived in the central stores yet.

A decision must be made on what should be done with the stocks of older-generation antimalarials in the public health stores when the new ACTs become available. For example, the phase-out plan may require that the health facilities give any remaining stocks of the current antimalarial to the central stores when they receive the stocks of the ACTs. The central stores would then be responsible for the disposal of the old drug stocks.

Phasing out of the current antimalarials from the nonprofit private sector facilities may be done in the same way as in the public sector. As mentioned earlier, phasing out the current antimalarial from the for-profit private sector is more complex; it may be prudent to focus on the public and nonprofit sectors initially while developing long-term strategies for managing the for-profit sector.

Management of Artemisinin-Based Combinations Supply: Developing a Phase-In or Roll-Out Plan

Development of a Phased or Nationwide Implementation Program

The new policy can be implemented either through a phased implementation or through an immediate nationwide rollout. The decision on which method to use has implications for the technical and operational components listed in this framework.

1. Phased implementation plan, which can be done in two ways—

    a. Geographically: by selecting some areas for earlier implementation than others

    b. System-based: by selecting some parts of the health system for earlier implementation (i.e., first public health services or first public health and community-based services)

    The advantages of a phased implementation include—

    - Lower start-up costs for the implementation.
    - The dissemination of the STGs, the training of the health workers, and the BCC strategies can be tested and any problems with the materials or methods identified and corrected.
    - The uptake of the new policy in the health facilities can be monitored and modeled—including getting a better idea of whether the availability of effective antimalarial treatment in the public sector health facilities increases use of the public health facilities—thus allowing for better forecasting of the demand for the ACTs.

2. Nationwide implementation plan—which is the rollout of the new policy in the entire country at the same time. It requires greater start-up costs and better coordination of guidelines dissemination, health worker training, and availability of antimalarials at the health facilities to ensure that the implementation is successful.

Forecasting of Demand and Quantification

For the immediate future, the GFATM is likely to be the major source of external funding for countries for the purchase of ACTs. Proposals to the GFATM must include accurate demand forecasts for antimalarials. Annex 3 provides tables that can be used to develop forecasts for ACT needs. Table 1 of the annex contains information on the current procurement for all antimalarials using GF funds, and Tables 2a and 2b contain estimated numbers of ACT requirements for the first and second 12 months, respectively.

Key questions to consider when making the forecasts are listed Box 7.

Box 7. Key Questions to Be Considered When Making Forecasts of the Potential Demand for ACTs

- What method is currently used for forecasting of antimalarials?
- How are forecasts validated and how is the data managed?
- Are adequate buffer stocks planned at relevant levels?
- Are parallel procurement efforts for national procurements as well as grants appropriately harmonized?
- What method of quantification will be used to determine the estimates and what are the data limitations?
- What will be the diagnostic criteria for malaria under the new policy; that is, is there a need to estimate the requirements of rapid diagnostic tests and/or commodities for microscopy as well?
- Will the implementation be piloted in a few districts then scaled up gradually throughout the country, or will there be a nationwide rollout?
- What is the expected uptake of the new policy over time within each health facility and/or district?

Several different methods can be used to compile a needs forecast, including consumption-based methods and morbidity-based methods. When a new drug policy is implemented, data on past consumption are not available. In this case, the appropriate method of forecasting is morbidity. This method may be compared using adjusted consumptions based on consumption of previously used first- and second-line treatments. Getting adequate morbidity data can be a challenge because of the potential inaccuracies of the data in the health management information systems (HMISs), and often reasonable estimates must be made from whatever data do exist. In using morbidity data to develop forecasts for malaria, there must be a clear understanding of the source of the morbidity data and the treatment-seeking behaviors with respect to malaria in the country. HMISs usually collect data from the public health facilities only, possibly resulting in an under-representation of the morbidity burden of malaria in the country. There is some anecdotal data to

suggest that the availability of an effective antimalarial at the public health facilities, at a lower cost than would be available in private health facilities, may increase utilization of the public health facilities; some provision may need to be made to prepare for this possibility. A phased implementation has the advantage of allowing data to be collected that would enable better estimates to be made of the uptake of the new policy at the health facilities, thus improving the estimates of the potential demand before the nationwide implementation.

A decision to change the diagnostic criteria for malaria from a reliance on clinical diagnosis to the use of biological diagnostic criteria (RDTs or microscopy) also affects the different forecast methods. The use of morbidity data collected on the basis of a clinical diagnosis of malaria may lead to an overestimation of the demand for ACTs because clinical diagnosis results in more false positives than a biological diagnosis; allowances would need to be made for this potential overestimation when performing the forecasting exercise. The planned use of biological diagnosis also means that needs forecasting of the RDTs and/or other commodities for microscopy would need to be done.

The complexities associated with forecasting demand mean that a need may exist to develop preliminary estimates of future demand of ACTs for submission to suppliers, but these estimates need to be subjected to an ongoing review and adjustments made as needed when new information becomes available. Various tools and methodologies can be used in developing forecasts for antimalarials (MSH and WHO 1997; WHO 1995). Technical assistance with compiling these forecasts should be sought before applications are made to the GFATM or other funding organizations. The process of getting the data on morbidity and/or past consumption as well as quantification can take about three months.

The forecasts can then be used to cost out the requirements and quantification can be carried out based on available budget.

Procurement

"An effective procurement process ensures the availability of the right drugs, in the right quantities, at reasonable prices, and at recognized standards of quality" (MSH and WHO 1997). The key questions that need to be asked in developing a procurement plan for the ACTs are listed in Box 8. For noncoformulated ACTs, before procurement can occur, the decision must be made on whether the drugs should be prepackaged. This factor will affect the selection of the supplier. If drugs will be procured "loose" and then prepackaged, a manufacturer that can prepackage must be identified, and labeling and package inserts must be developed and pretested. The quantification of the ACTs needs has been discussed in the preceding section, and the distribution of the ACTs is discussed in the next section. This section focuses on the steps involved in purchasing the ACTs.

For procurement using GF funds, it is important to adhere to GF policies on procurement and supply management, which can be downloaded from the GF Web site (www.theglobalfund.org). Among other points, the policy emphasizes the purchase of products that have been prequalified by WHO.

Often, actual procurement and financing of the procurement occur in different departments or ministries. There is a need to coordinate activities to ensure synchronization between the financing activities and the requirements of the procurement cycle.

Box 8. Key Questions on Procurement of ACTs

- What procedures and/or systems exist for managing the procurement process?
- Is the system transparent and efficient?
- What is the anticipated duration of the procurement cycle from product selection to the arrival of goods?
- Are there systems in place for monitoring supplier performance and enforcing the procurement contracts?
- What will be the diagnostic criteria for malaria under the new policy; that is, is there a need to procure RDTs and/or commodities for microscopy as well as the drugs?

A procurement plan that considers the distribution strategy[5] must be developed. This procurement plan must also include information on the procurement method to be used—that is, whether to use open tender, restricted tender, competitive negotiation, or direct procurement. A detailed discussion on the advantages and disadvantages of these methods can be found in other resource texts (see MSH and WHO 1997). To obtain the best prices, however, competitive procurement is generally recommended (the limited number of suppliers of ACTs at this time may mean that the cost benefits of competitive procurement may not always be achieved). Irrespective of the procurement method selected, systems need to be put in place to ensure that the products procured are of appropriate quality. This may be achieved either through prequalification[6] or postqualification of suppliers as part of the competitive bidding process. Additionally, there must be a system in place for monitoring supplier performance and for resolving any problems identified as a result of this monitoring. Countries may require technical assistance to prepare the tender documents for procurement and to manage the procurement process. WHO and the United Nations Children's Fund (UNICEF) have negotiated prices with one prequalified supplier and will make time-limited agreements with quality-assessed suppliers in order to allow supply of quality-assessed formulations to the programs. This method of procuring ACTs may be the easiest. In addition, the GF is coordinating with grantees to establish an "ear-marked" pool of funds for procurement of ACTs.

Malaria Medicines Supply Service

The RBM partnership is establishing the Malaria Medicines Supply Service (MMSS), which will provide support to malaria-endemic countries to ensure the availability of affordable quality antimalarials and other malaria commodities, including RDTs and insecticide-treated nets

[5] For both public and private sectors.

[6] WHO has prequalified one supplier of ACTs—Novartis®, has quality assessed the products of IPCA and CIPLA, and is developing a pool of other prequalified suppliers to assist countries in this process. (See <www.rbm.who.int.mmss>.)

(ITNs). The capabilities of the various partners will be drawn upon to accomplish this. UNICEF or WHO, for example, may be drawn upon to support procurement. It is expected that the MMSS will be fully functional by the end of 2004. The exact *modus operandi* for this facility is currently being developed, and subsequent revisions of this document will address this area of support as it evolves.

Distribution

The detailed steps in the distribution of antimalarials will differ from country to country, depending on how the public and private distribution systems are organized, and whether or not a central medical store plays a role in the distribution system. (In a "pull" system, the health facilities order drugs from the stores or suppliers based on their own determination of their needs. In a "push" system, the central store determines the supplies to be sent to each health facility based on the information it has received about the needs at the health facilities.) The short shelf life of ACT (12–24 months) makes it imperative that distribution systems function effectively to avoid drug loss due to expiry.

Box 9. Key Questions for Distribution

- Is there a comprehensive distribution strategy and a detailed distribution plan?
- Does the plan ensure that medicines will get to dispensing points at least several months before expiry?
- Does the plan allow for effective coordination/collaboration between the public and private sectors?
- Is there existing capacity (public and/or private) to implement the distribution plan?
- Are the storage capacity and conditions adequate and appropriate? If not, what plans exist to improve them?
- What is the distribution and transportation capacity and is it adequate?

Provided the drugs are in stock at the central medical store, distribution to the peripheral level can take two to four weeks or more. For example, in Zambia, facilities must request a product, then it is delivered in one month through a central or cascade system.

The distribution plan should also take into account the private sector. Unavailability of the product in the private sector encourages leakage as well as the use of monotherapies.

Inventory Management

Inventory management measures need to be assessed and upgraded, or need to be established if they do not already exist, at all health facilities to ensure that stocks of antimalarials are managed appropriately to prevent stock-outs and to ensure that wastage due to expiry is minimal. Key questions are listed Box 10.

Box 10. Key Questions for Inventory Management

- What inventory control mechanism is in place and is it reliable? Is a physical check of drugs carried out at least annually?
- What is the average stock turnover time and is there a policy and practice of issuing stock according to first expiry/first out at all levels?
- Are there functional managing information systems to manage product flow?
- How well is the shelf life of products managed throughout the existing supply chain? What systems are in place for dealing with expired products?
- Are adequate security measures in place to prevent theft of stored products?

Mechanisms will be needed to ensure that records are kept and updated regularly and that physical checks are regularly preformed. Provisions must be made to prevent diversion of drugs from the public facilities to the private sector. Furthermore, due to the short expiry of ACTs, it will be essential to strengthen drug management systems to ensure that products do not expire before they are used and to efficiently remove any expired stock from the facilities and stores. Provisions for recalling short-expiry products in districts or facilities with low utilization and transferring them to those areas with high utilization may need to be put in place.

Quality Assurance

The main quality assurance issues that must be addressed during the process of policy change are related to product efficacy (drug resistance monitoring), product safety (pharmacovigilance), product quality at registration and/or procurement, and postmarketing quality surveillance systems. Most countries already have surveillance systems that monitor product efficacy, and these systems may need to be strengthened. Building capacity in existing structures that collect similar information for other essential medicines could be considered in order to make the best use of available human resources.

Box 11. Key Quality Assurance Questions

- Is there a system or procedures in place for monitoring the efficacy of the drugs?
- Is there a system or procedures in place for reporting adverse effects of drugs?
- Is there a system or procedures in place for monitoring the quality of drugs during registration and/or procurement?
- Is there a system or procedures in place for monitoring the quality of drugs already in the market? Are samples regularly tested by a qualified laboratory?

Pharmacovigilance

Mechanisms must be in place for surveillance of adverse events associated with the use of the ACTs.[7] This monitoring may be ensured by the establishment of a regular reporting system through the health facilities and/or through special studies. This system for monitoring adverse events of ACTs must be developed within the systems for monitoring adverse events for other drugs. Forms for recording adverse events should be provided to the health facilities. At each level of the health system, a point person must be appointed to collate the data and a system must be developed for reporting back to the central level.

Product Quality Surveillance System

Product quality surveillance must be integrated at all levels of the health system to ensure that the drugs available in the market are of the appropriate quality. A comprehensive system includes ensuring quality during drug registration, procurement, and distribution through the public and private sectors; it also includes a mechanism for removing from the supply chain any products found to be of inappropriate quality and that pose a danger to the health of those who use them.

Monitoring and Evaluation

Monitoring and evaluation (M&E) is an essential part of the reprogramming process and occurs throughout planning and implementation. Planning for evaluation and monitoring needs to be done early and integrated throughout the implementation process, so that data generated from monitoring can be used to guide any changes in implementation strategies by malaria programs, governments, and external stakeholders. M&E is particularly important for ACTs, because health care workers have little experience with their use. Proposals for reprogramming should have a strong M&E component. Some key questions related to the development of M&E systems are listed in Box 12.

Box 12. Key Questions for Monitoring and Evaluation Systems

- Is there an M&E plan to track implementation progress and performance relative to defined/established targets?
- What information sources exist for monitoring, and what needs to be developed?
- How will performance be evaluated?
    - Internal vs. external evaluation?
    - Process vs. outcomes evaluation?

[7] The artemisinins are currently not recommended for use in the first trimester of pregnancy. It is likely that they will, however, be given to a cohort of the pregnant population unaware of their pregnancy. A system should be in place to detect adverse effects that may arise in the course of using the ACTs.

Data for monitoring and evaluation can be obtained from existing surveys, such as Demographic and Health Survey (DHS) and HMIS data, or through special studies. The decision on which information source(s) to use depends on each country context and the type of information systems available. Types of information systems include—

- *DHS:* DHS surveys are nationally representative household surveys and provide data for a wide range of monitoring and impact evaluation indicators. Typically, these surveys are conducted every five years in most endemic countries.

- *HMIS:* Most countries have an existing HMIS system that provides basic information on mortality and morbidity rates.

- *Drug Management Information Systems:* These systems may exist to provide information on management of drug supplies.

- *Malaria information system:* Some countries have a sentinel system that collects routine malaria information from selected health centers. Information on drug availability and other indicators of change may be available or may be incorporated into this system.

- *Adverse drug reaction/pharmacovigilance reporting systems*

- *Special studies:* In the absence of good data to monitor the uptake of the policy, it may be necessary to carry out special research to obtain particular data. Such data are collected every five years in most endemic countries.

Some sample M&E indicators are listed in Annex 4.

ANNEX 1. CHECKLIST OF KEY ACTIONS (ILLUSTRATIVE)

This table is a template with illustrative activities that countries may use in developing their implementation plans. The list of activities is not comprehensive; a list should be tailored to the specific country context.

Issues	Key Actions	Technical/Operational Lead	Estimated Timeline	Resource Requirements
Planning and coordination mechanisms	Identify stakeholders			
	Determine their importance at the various stages, their roles and responsibilities, and how they should be engaged (stakeholder analysis)			
	Identify composition of transition committee or, if using an existing mechanism, determine which existing committee or group should carry out this process			
	Establish working groups or task forces and their respective membership within the committee			
	Establish terms of reference for working groups/task forces			
	Develop/review mode of work and frequency of meetings			
Financing	Develop/review budget for transition and implementation			
	Identify potential national-level resources—e.g., Heavily Indebted Poor Country (HIPC) Trust Fund			
	Evaluate current spending profile and redirect funds if necessary			
	Develop a strategy for accessing funds			
	Develop/review proposals for GFATM (see below) or other funding agency			
	Identify commitments from departments within MOH and from donors			
	Evaluate cost-sharing and exemption mechanisms and develop methods for improving equity			
	Develop/review financial accountability mechanisms			

Issues	Key Actions	Technical/Operational Lead	Estimated Timeline	Resource Requirements
Revision of drug regulation	Register new drug (if there is a system of registration)			
	Establish fast-track registration system as needed			
	Evaluate whether regulatory requirements may have a negative impact on implementation and establish mechanisms to alleviate this			
	Evaluate and strengthen regulatory enforcement capacity if needed			
	Promulgate regulations for appropriate importation, distribution, prescribing, and dispensing of ACTs and ensure that they are consistent with the policy			
Essential Medicines List and Standard Treatment Guidelines	Determine which guidelines need to be revised			
	Determine the process for revision and the groups involved			
	Determine whether new guidelines need to be published or an addendum made to the existing guidelines			
	Publish revised guidelines/EML and/or addendum			
	Disseminate new guidelines and EML			
	Revise pre-service and in-service training curricula to incorporate new guidelines			
	Develop/review plan for training health workers and develop training materials			
	Convene training workshops soon after procurement of the new antimalarial and carry out a cascade training			

Issues	Key Actions	Technical/Operational Lead	Estimated Timeline	Resource Requirements
Behavior change communication/Information, education, communication	Develop/review BCC strategies, and coordinate with IEC strategy			
	Develop/review IEC strategies			
	Develop/review plan for implementing the BCC strategies			
Phasing out old drugs	Determine pipeline for the “old” drug through central- and peripheral-level data collection			
	Adjust future procurements of the current drugs to make sure that large pipelines of old drug do not accumulate when the new drug is procured			
	Develop/review a plan for the phase-out of the current drug from the health system as the new drug becomes available			
	When policy change occurs, withdraw old drug from peripheral areas following the phase-out plan			
Quantification	Obtain consumption data and/or morbidity data from the field			
	Use this data to calculate potential consumption for a phased or nationwide implementation, allowing for some buffer stock and keeping in mind the short shelf life of ACTs			
	Calculate potential consumption or rapid diagnostic tests if this diagnostic method is chosen and/or commodities for microscopy			
	Ensure that forecasts for parallel procurement efforts of the MOH and grants (including GF) are harmonized			

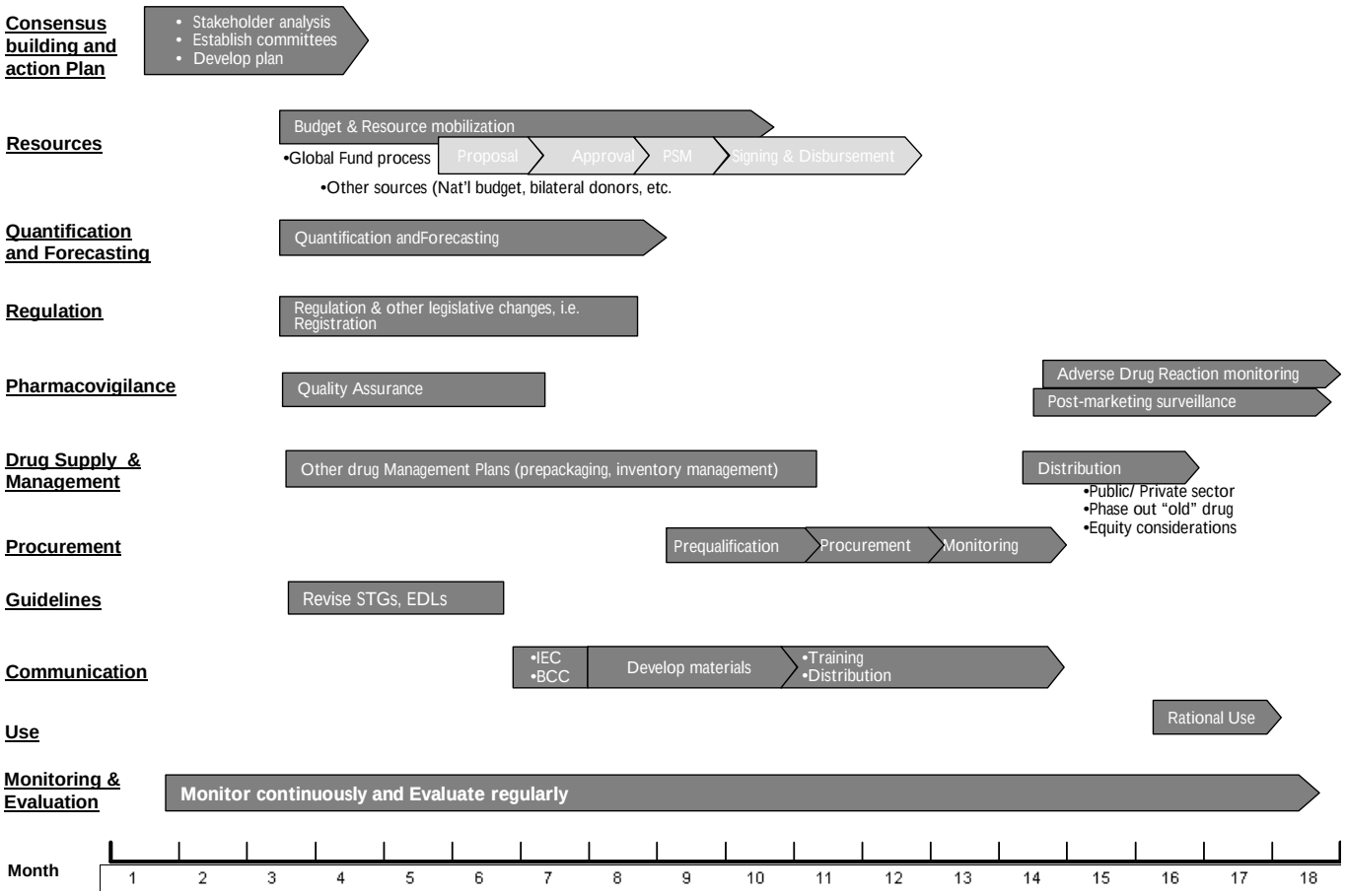
Issues	Key Actions	Technical/Operational Lead	Estimated Timeline	Resource Requirements
Procurement	If GFATM is the source of funding, follow the steps under GFATM requirements			
	Develop a procurement plan for antimalarials and diagnostic commodities			
	Review current procurement procedures, including efficiency and transparency, and identify weaknesses; develop mechanisms to address weaknesses			
	Identify source of technical assistance and obtain the technical assistance as needed			
	Process procurement through WHO or UNICEF if using artemether-lumefantrine			
	Determine if there is a need to prepackage the product and identify supplier(s) for a prepackaged product or identify a manufacturer that can prepackage			
	Develop packaging and labels for prepackaged product if needed and pretest these			
	Develop tender documents			
	Initiate and manage procurement			
	Supplier performance monitoring			

Issues	Key Actions	Technical/Operational Lead	Estimated Timeline	Resource Requirements
Distribution	Develop/review a distribution plan			
	Review/develop distribution systems to allow for coordination between the public and private sectors			
	Develop/review strategies to avoid leakage to the private sector			
	Develop/review storage capacity and conditions			
	Develop/review human capacity for efficient implementation of distribution plan and supervision			
	Develop/review transportation system			
	Develop/review redistribution systems and systems to remove expired stocks			
	Develop/review systems to monitor efficiency of distribution system and redistribution mechanisms			

Issues	Key Actions	Technical/Operational Lead	Estimated Timeline	Resource Requirements
Inventory management	Review/develop inventory management systems to improve the management of the drugs in the peripheral health facilities			
	Develop/review security measures to prevent theft or stored products			
	Develop/review systems to ensure management of the shelf life of products and develop/review systems for dealing with expired products			
Revision of quality assurance mechanism	Develop/review system for monitoring of adverse events			
	Develop/review systems for quality assurance during drug registration and procurement			
	Develop/review system for dealing with violations of drug quality standards			
	Establish mechanism to coordinate the various surveillance systems—adverse drug reaction, product quality, effectiveness, etc.			
	Develop/review plan for postmarketing product quality surveillance;ensure that samples will be regularly tested by a qualified laboratory			

Issues	Key Actions	Technical/Operational Lead	Estimated Timeline	Resource Requirements
M&E	Develop/review plan for postmarketing product quality surveillance			
	Define program milestones (indicators)			
	Identify data needs			
	Develop/adapt and implement information systems			
	Identify and address human and information technology resource needs			
	Develop schedule for M&E activities			

ANNEX 2. ILLUSTRATIVE TIMELINE FOR IMPLEMENTATION



ANNEX 3. GFATM QUESTIONNAIRE FOR GRANTEES

Questionnaire to GFATM Grantees that have purchased antimalarials OR will require ACTs *using GFATM Funds*

This questionnaire seeks to gather urgently needed information about the status of the procurement of artemisinin combination therapy (ACT) in countries that have been funded or are in the process of being funded by the Global Fund.

Please circle the answer to the questions below. For Question 2, please complete the corresponding tables on the following pages.

1. **Has procurement of any health products started?** *YES / NO*

2. **Has procurement of antimalarial products started?** *YES / NO*

   If YES, please complete Table 1 **and** Tables 2a and 2b.

   If NO, please complete Tables 2a and 2b only.

Table 1. Current Procurement of all antimalarials (ACT and non-ACT) WITH GF FUNDS
(first two shaded rows are provided as examples only)

Drug Name	Strength (1)	Unit (2)	Pack size	Pack Cost (USD)	Unit Cost[8] (3) USD	Number of Units (4)	Number of Packs	Total Cost (3) x (4) USD	Manufacturer / Supplier	Date of Purchase (dd/mm/yy)	Expected Stock-Out Date
Amodiaquine	*150 mg*	*Tab*			*0.01*	*230,000*		*2,300*	*Ipca*	*22/7/04*	*22/7/05*
Artemether-lumefantrine	*Co-formulated adult 35 kg+*	*Tab*	*10*	*2.40*	*0.24*	*2,470,000*	*247,000*	*592,800*	*Novartis / IDA*	*17/4/04*	*17/10/04*

[8] Indicates currency and exchange rate at time of procurement.

Table 2a. Estimated Number of ACT Treatments Required by Type of ACT and Age of Patient (First 12 months)

Month / Year													Total (Year 1)
	1	2	3	4	5	6	7	8	9	10	11	12	
Type of ACT: _____ (e.g., artesunate + amodiaquine, artemether/lumefantrine)													
Infant													
Child													
Adolescent													
Adult													
Type of ACT: _____ (e.g., artesunate + amodiaquine, artemether/lumefantrine)													
Infant													
Child													
Adolescent													
Adult													

Table 2b. Estimated Number of ACT Treatments Required by Type of ACT and Age of Patient (Second 12 Months)

Month / Year													Total (Year 1)
	13	14	15	16	17	18	19	20	21	22	23	24	
Type of ACT: _____ (e.g., artesunate + amodiaquine, artemether/lumefantrine)													
Infant													
Child													
Adolescent													
Adult													
Type of ACT: _____ (e.g., artesunate + amodiaquine, artemether/lumefantrine)													
Infant													
Child													
Adolescent													
Adult													

ANNEX 4. SAMPLE M&E INDICATORS

These indicators were developed through a collaboration between WHO, UNAIDS, GFATM, USAID, UNICEF, the World Bank, and other partners.[9]

	Service Delivery Area	Output	Outcome
Prevention	• Insecticide-treated nets (ITNs)	• Number of nets, long-lasting ITNs (LLITNs), pretreated nets, or re-treatment kits distributed* • Number of nets re-treated* • Number of sentinel sites established for monitoring insecticide resistance*	• Households owning ITNs (Malaria-PI 1) • Children under 5 using ITNs (Malaria-PI 2)
	• Malaria in pregnancy	• Number of nets, LLITNs, pretreated nets or re-treatment kits distributed* • Number of nets re-treated* • Number of pregnant women receiving correct IPT*	• Pregnant women using ITNs (Malaria-PI 3) • Pregnant women receiving intermittent preventive therapy (IPT) (Malaria-PI 4)
	• Prediction and containment of epidemics		• Malaria epidemics detected and properly controlled (Malaria-PI 5)
	• Indoor residual spraying	• Number of homes and areas sprayed with insecticide*	
	• Behavior change communication (BCC)	• Number of targeted areas with BCC services*	

Table continues

[9] Global Fund to Fight AIDS, Tuberculosis and Malaria. 2004. *Monitoring and Evaluation Toolkit: HIV/AIDS, Tuberculosis and Malaria.* <http://www.theglobalfund.org/pdf/guidelines/pp_me_toolkit_en.pdf> (accessed Aug. 10, 2004).

	Service Delivery Area	Output	Outcome
Treatment	• Prompt, effective antimalarial treatment	• Number of patients with uncomplicated and severe malaria receiving correct diagnosis and treatment* • Health facilities with no reported stock-outs of antimalarial drugs (Malaria-TI2)	• Children under 5 years of age with access to prompt, effective treatment (Malaria-TI1) • Patients with severe malaria receiving correct treatment (Malaria-TI3)
	• Monitoring drug resistance	• Number of patients with uncomplicated and severe malaria receiving correct diagnosis and treatment* • Health facilities with no reported stock-outs of antimalarial drugs (Malaria-TI2)	
	• Home-based management of malaria	• Number of caretakers recognizing signs and symptoms of malaria*	

***** Outputs and outcomes here are also measured as "counts" of increased capacity provided against a need that has been estimated as a pre-condition for change, and they can be quantified through direct observation or an annotated inventory. For these "counts," the toolkit **does not** provide a detailed description in the annexes.
****** Both percentages and numbers ("counts") are required. However, if a denominator cannot be obtained, focus should be on the "count."

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